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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,205	10/20/2000	Thomas J. Hudson	2825.1021-003	7268

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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.  
530 VIRGINIA ROAD  
P.O. BOX 9133  
CONCORD, MA 01742-9133

EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/17/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/693,205

Applicant(s)

HUDSON ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 April 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 13-22 and 24-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                     | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5 and 11</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicants' election of Applicant's election of Group I, claims 1-12 and 23, and SEQ ID NOs:7 and 47 in Paper No. 13 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Informalities***

2. The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (page 42, lines 22-28). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2-4 and 6-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2-4 and 6-8 are directed to a nucleic acid comprising an exon from a vertebrate gene wherein the exon is at 1150 base pairs; a portion of a nucleic acid is at least 10 nucleotides of SEQ ID NO:7 or of the complement of SEQ ID NO:7; a nucleic acid comprising a nucleotide

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sequence, which has at least 60% sequence identity to SEQ ID NO:7 or a complement of SEQ ID NO:7; and a nucleic acid which hybridizes under stringency conditions to a nucleotide sequence of SEQ ID NO:7 or of the complement of SEQ ID NO:7. The specification indicates that the variants of the nucleic acid comprising a portion of an exon from a vertebrate gene, a spastin gene, a portion of the gene, a nucleotide sequence having at least 60% sequence identity to the claimed sequences such as SEQ ID NO:7, or a fragment of SEQ ID NO:7 (page 2, line 22-page 3, line 21; page 17, lines 5-10). However, the specification does not specify which portion of the nucleic acid is identical to SEQ ID NO:7 or which portion of the exon from a vertebrate gene is part of spastin gene. There is no disclosure indicating the nucleic acid having at least 60% sequence identity to SEQ ID NO:7 or the fragments of SEQ ID NO:7 can encode a protein having the same function as SEQ ID NO:8, which is encoded by SEQ ID NO:7. Without guidance on the identities of the nucleic acids having at least 60% sequence identity to SEQ ID NO:7 or of fragments of SEQ ID NO:7, one skilled in the art would not know which region of SEQ ID NO:7 is essential for coding a functional protein. The lack of representative species for the nucleic acid having at least 60% sequence identity to SEQ ID NO:7 or for fragments of SEQ ID NO:7 as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1, 5-12 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5-12 and 23 are indefinite because the claim contains non-elected sequences. Claims 9-12 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

5. Claim 2 is indefinite because of the use of the term “at least”. The term “at least” renders the claim indefinite, it is unclear what is the upper limit for the numbers of bases pairs in the exon.

6. Claim 6 is indefinite because of the use of the terms “at least about” and “portion”. The term “at least about” and “portion” renders the claim indefinite, it is unclear how many nucleotides are as a portion of a nucleic acid, and whether the portion is greater than 10 nucleotides as to “at least” or less than 10 nucleotides as to “about”.

7. Claim 7 is indefinite because of the use of the term “at least about 60% identical to a nucleotide sequence”. The term “at least about 60% identical to a nucleotide sequence” renders the claim indefinite, it is unclear whether the nucleic acid is identical to SEQ ID NO:7 or has 60% sequence homology to SEQ ID NO:7 as to “60% identical”, and whether the sequence homology is greater than 60% as to “at least” or less than 60% as to “about”. The term “identical” is an absolute term, use of “sequence homology” or “sequence identity” is suggested.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 6 is rejected under 35 U.S.C. 102(a) as anticipated by Nagase *et al.* (DNA Research 5, 277-286 (October 1998)).

Nagase *et al.* disclose a Homo sapiens mRNA for KIAA070 protein (accession No. AB018273; Tables 1 and 2), which has 100% sequence homology to the nucleotides 12200-12792 of SEQ ID NO:7 (see sequence match result; claim 6).

9. Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as anticipated by Desseyn *et al.* (J. Biol. Chem. 272, 3168-3178 (1997)).

Desseyn *et al.* disclose the central exon of human mucin Gene MUC5B contains 10,713 base pairs (page 3169, left column; page 3173 right column; claims 2 and 3), which codes for a 3570 amino acids peptide.

10. Claim 6 is rejected under 35 U.S.C. 102(b) as anticipated by Bouillaud *et al.* (Gene Bank Accession No. R17106, last updated June 12, 1996)).

Bouillaud *et al.* disclose a mRNA sequence, a Homo sapiens cDNA clone 20108, has 32.7% sequence homology to nucleotides 5300-6700 of SEQ ID NO:7, the sequence of R17106 contains the same portion of at least 10 nucleotides as SEQ ID NO:7 (see sequence match result; claim 6).

### ***Conclusions***

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11. No claims are allowed.

*Art of Record*

Sequence search has been performed on SEQ ID NO:47 and nucleotides 1-500, 5300-6700 and 12200-12792 of SEQ ID NO:7, and there is no single nucleotide sequence matching all three portions of SEQ ID NO:7. Therefore, it appears nucleic acids of SEQ ID NOs:7 and 47 are free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.  
Patent Examiner

CMK

  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER

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June 12, 2002